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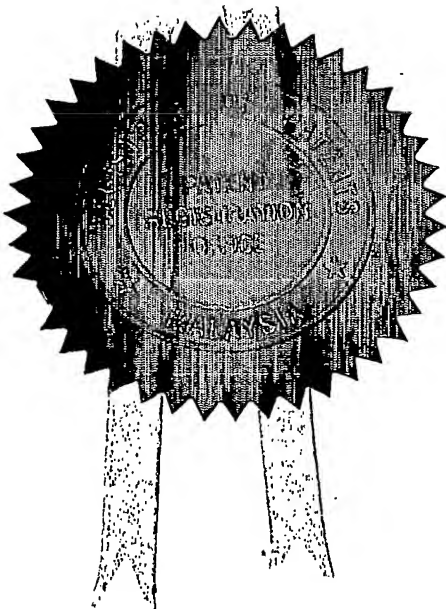
PATENT APPLICATION NO: PI 2002 2342

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By authority of the
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ABDUL RAHMAN RAMLI
(CERTIFYING OFFICER)

17 December 2003



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Ministry of Domestic Trade and Consumer Affairs Malaysia
Intellectual Property Division.


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CERTIFICATE OF FILING

APPLICANT : MOO YOON NGEK
APPLICATION NO. : PI 20022342
REQUEST RECEIVED ON : 21/06/2002
FILING DATE : 21/06/2002
AGENT'S/APPLICANT'S : PIP/0813/IPPF/02/LCH/YAN
FILE REF.

Please find attached, a copy of the Request Form relating to the above application, with the filing date and application number marked thereon in accordance with Regulation 25(1).

Date : 10/07/2002


.....
(SHAMSIAH BT KAMARUDDIN)
for Registrar of Patents

To : LOK CHOON HONG,
C/O PINTAS CONSULTING GROUP SDN BHD.,
SUITE 6.03, 6TH FLOOR,
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MALAYSIA.

Patents Form No. 1
PATENTS ACT 1983

REQUEST FOR GRANT OF PATENT
[Regulations 7 (1)]

To: The Registrar of Patents
Patent Registration Office, Kuala
Lumpur, Malaysia

For Official Use

Pi 2002 2342
Application received on : 21/6/52

Fee received on : 21/6/02

Amount : RM 200

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RHB 77C 835

Please submit this Form in
duplicate together with the
prescribed fee.

Applicant's or Agent's file
reference

PIP/0813/IPPF/02/LCH/Yan

THE APPLICANT (S) REQUEST (S) THE GRANT OF A PATENT IN RESPECT OF THE
FOLLOWING PARTICULARS:

I. Title of Invention: PRECISION CONTOURED EXO/ENDOCERVICAL CELL
SAMPLER

II. APPLICATION(S) (the data concerning each applicant must appear in
this box or, if the space is insufficient, in the space below):

Name of Applicant : MOO YOON NGEN

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Nationality: Malaysian

* Permanent residence or principle place of business:

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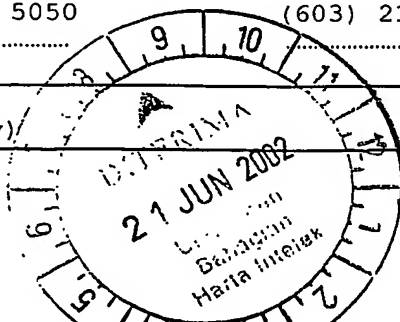
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Additional Information (if any)



20022342

III. INVENTOR:

Applicant is the inventor: Yes ☒ No ☐

Name of inventor

Address:

MOO YOON NGEN

112, JALAN JALAK, TAMAN BUKIT MEWAH,
5½ MILES, JALAN CHERAS,
56100 KUALA LUMPUR, MALAYSIA.

A statement justifying the applicant's right to the patent
Accompanies this Form:

Yes

☐

No

☒

Additional Information (if any)

IV. AGENT OR REPRESENTATIVE:

Applicant has appointed a patent agent in accompanying Form
No17

Yes

☒

No

☐

Agent's Registration No: PA/99/0077
Applicants have appointed: LOK CHOON HONG
To be their common representative.

V. DIVISIONAL APPLICATION:

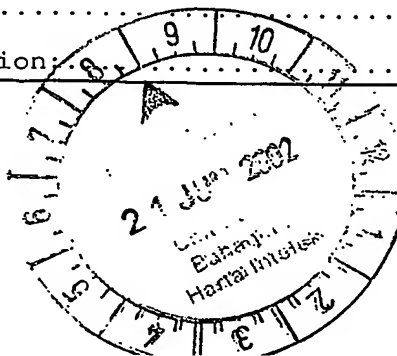
This application is a divisional application ☐

The benefit of the filing date ☐ priority date ☐

Of the initial application is claimed in as much as the subject-
matter of the present application is contained in the initial
application identified below:

Initial Application No.:

Date of filing of initial application:



00022342

VI. DISCLOSURES TO BE DISREGARDED FOR PRIOR ART PURPOSE:

Additional information is contained in supplemental box:

(a) Disclosure was due to acts of applicant or his predecessor in title

Date of disclosure:

☐

(b) Disclosure was due to abuse of rights of applicant or his predecessor in title

Date of disclosure:

☐

A statement specifying in more detail the facts
Concerning the disclosure accompanies this Form

Yes

☐

No

☒

Additional Information (if any)

VII. PRIORITY CLAIM (if any):

The priority of an earlier application is claimed as follows:

Country

Filing Date

Application No.

-

-

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Symbol of the international Patent Classification:
If not yet allocated, please tick

☐

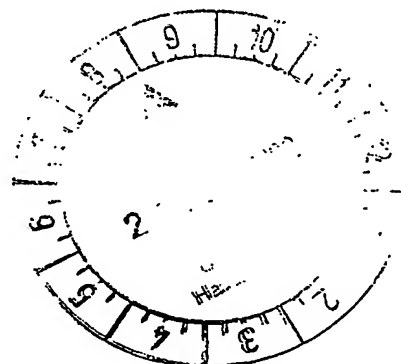
The priority of more than one earlier application is claimed:

☐

The certified copy of the earlier application (s) will furnished
by the patent agent upon request

☐

Additional Information (if any)



VIII CHECK LIST

A. This application contains the following:

| | | |
|----------------|----------|--------|
| 1. Request | 4 | sheets |
| 2. Description | 6 | sheets |
| 3. Claim | 2 | sheets |
| 4. Abstract | 1 | sheet |
| 5. Drawings | <u>1</u> | sheets |
| Total | 14 | sheets |

This Form, as filed, is accompanied by the items checked below:

| | |
|---|-------------------------------------|
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| (b) declaration that inventor does not wish to be named in the patent | <input type="checkbox"/> |
| (c) statement justifying applicant's right to the patent | <input type="checkbox"/> |
| (d) statement that certain disclosures be disregarded | <input type="checkbox"/> |
| (e) priority document (certified copy of earlier application) | <input type="checkbox"/> |
| (f) cheque | <input checked="" type="checkbox"/> |
| (g) other documents (specify) | <input type="checkbox"/> |

IX.

SIGNATURE.....

LOK CHOON HONG

Agent's Registration No.: PA/99/0077

20/6/02

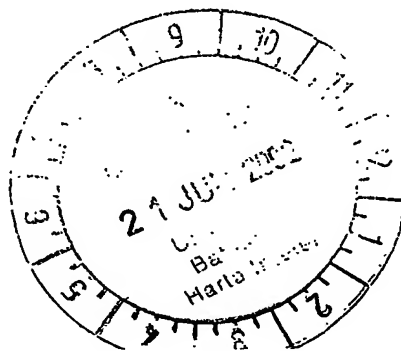
(Date)

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1. Date application received :
2. Date of receipt of correction, later filed papers or drawings completing the application :

* Delete whichever does not apply.

** Type name under signature. Pursuant to regulation 24, a declaration of withdrawal must be signed by the applicant (s) or by the agent so authorized for that specific purpose.



200221

Precision contoured EXO/ENDOCervical cell sampler

Field of Invention

5 The invention relates to a specific device for collecting representative cell samples from exocervix and endocervix for cytological microscopic examination, particularly for the purpose of pre-malignant and malignant diagnosis.

10 **Background of the Invention**

Occurrence of uterine cervical cancer is high among women and the rate has been increasing. The disease becomes the main cause of cancer death among women in Malaysia. Of vital
15 important, women are advised to have periodical medical pelvic examinations for early detection and prevention of uterine cervical cancer.

Many devices have been invented for sampling of representative
20 cells from the uterine endocervix and exocervix for the purpose of pre-malignant and malignant diagnosis. Such devices are generally having an elongated stem with a portion at one end, which is designed as a swab, spatula or a brush. However, drawbacks have been reported from these conventional
25 techniques. The swab technique has the disadvantages that the stick may break when abrasive force is applied to enable specimen sampling and extra time-consuming step is required to examine the mixing of desired and undesired cells on a microscope slide. In addition the cotton buds swab stick is
30 also unsatisfactory in retaining and transferring of cellular samples due to its rather tightly-wound and very absorbent ball-like surface. It has also a very limited contact with the exocervix.

The spatula technique enables cell sampling even from deeper cell layers, however, such device may cause post-exam bleeding or abrasion at the sampling spot. In addition the wooden or plastic spatulas are too stiff and rigid to provide an even and thorough scraping of the unevenly contoured uterine cervix. It is also less efficient in transferring the cellular samples onto the glass slides due to its inflexible L-shaped end portion.

Cellular samples obtained by the brush technique are usually overly blood-stained and a fair number of critical cervical cells are being trapped in between the bristles and hence do not get transferred fully onto the glass slides and therefore are wasted and lost for diagnosis. The brush device has also a very limited contact with the exocervix.

Summary of the Invention

The primary object of this invention is to provide a new and improved cell sampler to collect representative cell samples from the exocervix and endocervix for cytological microscopic examination. It involves only a simple "one-step" operation where a single insertion into the cervical canal can obtain both exocervical and endocervical cell samples.

Another object of this invention is to provide a cell sampler that holds securely at the exocervix and prevent excessive penetration into the internal os.

Still another object of this invention is to provide a cell sampler having an endocervical contact portion that is safe in use, thereby provides more comfort and less abrasive when making a complete 360 DEG rotational sweeping-up of all the representative cells.

Yet another object of this invention is to provide a cell sampler that is capable of collecting cells from deep inside body cavities due to the semi rigid vertical reach of the endocervical contact portion.

5

A further object of this invention is to provide a cell sampler that allows combined yet separated cell samples from both exocervical and endocervical regions with just a single swipe onto a microscope slide where these cellular portions
10 are clearly visible.

A still further object of this invention is to provide a cell sampler having a slightly thickened-handle to enhance better finger grip and optimal rotational manipulation.

15

These and further objects, features and advantages of the present invention will become apparent from the following description when taken in connection with the accompanying drawings which, for purposes of illustration only, show the
20 preferred embodiment in accordance with the present invention.

Brief Description of the Drawings

FIG. 1 is a perspective view of the present cell sampler for
25 sampling purpose.

FIG. 2 is a perspective view of the present cell sampler for spreading purpose.

30 FIG. 3 illustrates the transfer of samples onto a microscope slide.

FIG. 4 illustrates the rotational mechanism of the vertical contact portion of the present cell sampler.

Detailed Description of the Invention

With reference to the figure 1, the drawing shows an embodiment comprises an elongated and rounded stick-shaped stem (1) having a slightly thickened handle means (2) at bottom end to enhance better finger grip and optimal rotational manipulation. At the top end of said stem (1) is connected to an abrading means (3). The said abrading means (3) comprises a connecting means (4) and a functional L-shaped cell collecting means (5). The functional L-shaped cell collecting means (5) comprising of a vertical ENDOcervical contact portion (6) therein to aid in insertion of said cell sampler into the endocervix and configured to scrape cytology cell samples onto its surface when said cell sampler is rotated; and a horizontal EXOcervical contact portion (7) therein to aid in hugging the exocervix and scraping cytology cell samples onto its surface when said cell sampler is rotated.

The said vertical endocervical contact portion (6) is connected to the horizontal exocervical contact portion (7) by attachment means, preferably a predetermined, semi-tightened ball joint thus allowing the said vertical contact portion to has a 90 degree free moving angle with the respect to the horizontal exocervical contact portion (7) as shown in figure 4. The vertical endocervical contact portion (6) can stay critically upright while performing its cell sampling rotational scraping function and also enable to made instantly collapsible to a horizontal position onto microscope slide with just very slight finger pressure thus accomplishing its excellently designed objective of spreading the exo/endocervical cells speedily, smoothly and easily onto a microscope slide without the slightest hindrances. The attachment means also could be any fasteners, screws, snaps,

clamps, clips, nuts or other such equivalents that could used to secure one surface to another and rotational movements with respect to the horizontal exocervical contact portion (7) are allowed.

5

The connecting means (4) having one end which is connected to said stem (1) is rounded in cross sectional shape and the other end is a flattened end. Supported one top of the said flattened end is said functional L-shaped cell collecting means (5). The said flattened end of the connecting means (4) comprising of a supporting protrusion (8) at one edge of said flattened end and a retaining protrusion (9) at the other edge of said flattened end. The said EXOcervical contact portion (7) is attached to the supporting protrusion (8) of said connecting means (4).

The functional L-shaped cell collecting means (5) is coated with resilient material such as sponge, foam, fibre, silicon, PVC film, rubber, soft plastics and the like, thereby provide more comfort and less abrasive, yet direct and gently hugging to the critical transformation zone (T-zone), thereby allowing a thorough and complete 360 DEG rotational sweeping-up of all the truly representative cells. The retaining protrusion (9) of said connecting means (4) being configured to prevent excessive penetration of said cell sampler into the endocervix and lend resistance to the collapsible of said vertical ENDOcervical contact portion (6).

Figure 2 shows a flattened portion of EXOcervical and ENDOcervical contact portions. After a smear sample has been taken from the cervical canal, the said cell sampler is withdrawn from the cervix and the vertical ENDOcervical contact portion (6) will immediately be bent and collapsed on top of a microscope slide (10) as shown in figure 3, becoming

a horizontal, straight and flat spreading strip to be gently swept across the full length of the microscope slide (10), demonstrating clearly a combined yet separated cellular portions from both the exocervical and endocervical regions.

5

The invention is advantageously for use in a simple "one-step" operation involving only a single insertion for sampling cells from exocervix and endocervix and obtain representative cells from both regions to be included on the same microscope slide.

10

It is to be understood that the present invention may be embodied in other specific forms and is not limited to the sole embodiment described above. However modification and equivalents of the disclosed concepts such as those which readily occur to one skilled in the art are intended to be included within the scope of the claims which are appended thereto.

15

Claims

1. A cell sampler comprising of:
a stick-shaped stem having a top and a bottom end;
5 a collecting means in a L-shaped configuration for collecting smear sample from cervical canal, whereby said collecting means having a flexible construction which can be bent and flattened into a straight shape for easily spreading said sample; and
10 a connecting means connected said collecting means to the top end of said stick-shaped stem.
2. The cell sampler as claimed in claim 1, wherein said L-shaped collecting means comprising of a horizontal contact
15 portion for hugging the exocervix and scraping cytology cell samples onto its surface when said cell sampler is rotated; and a vertical contact portion to aid in insertion of said cell sampler into the endocervix and configured to scrape cytology cell samples onto its surface when said cell sampler
20 is rotated.
3. The cell sampler as claimed in any claim 1 to 2, wherein said connecting means further comprising one end which is connected to said top of the said stick-shaped stem rounded in
25 cross sectional shape and the other end in a flattened shape end.
4. The cell sampler as claimed in claim 3, wherein said flattened end of said connecting means, comprising of a
30 supporting protrusion at one edge of said flattened end to support said horizontal contact portion of said collecting means and a retaining protrusion at the other edge of said flattened end to prevent excessive penetration of said cell sampler into the endocervix and lend resistance to the

collapsible of said vertical contact portion of said cell collecting means.

5 5. The cell sampler as claimed in any claim 1 to 4, wherein said stick-shaped stem is elongated and rounded in shape.

10 6. The cell sampler as claimed in any claim 1 to 5, wherein said bottom end of the stick-shaped stem is thickened to form a handle means for better finger grip and optimal rotational manipulation.

7. The cell sampler as claimed in any claim 1 to 6, wherein said connecting means is a narrow and flat piece.

15 8. The cell sampler as claimed in any claim 1 to 7, wherein said cell collecting means is coated with resilient material such as sponge, foam, fibre, silicon, PVC film, rubber, soft plastics and the like.

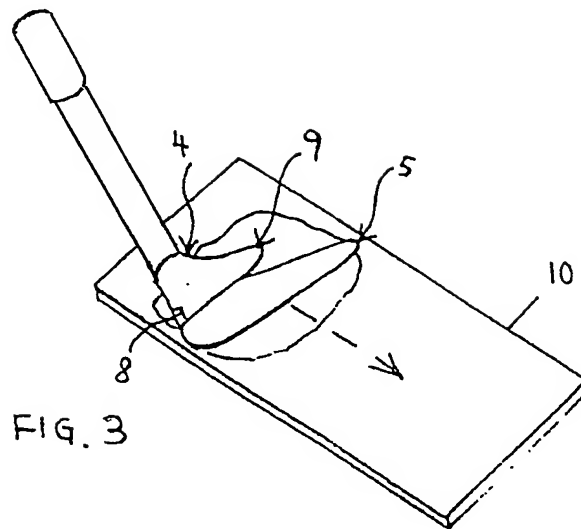
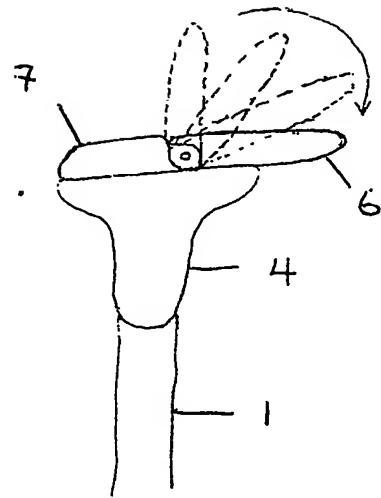
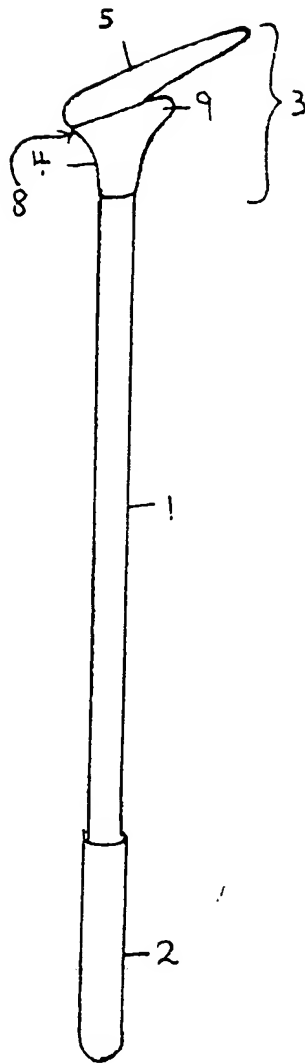
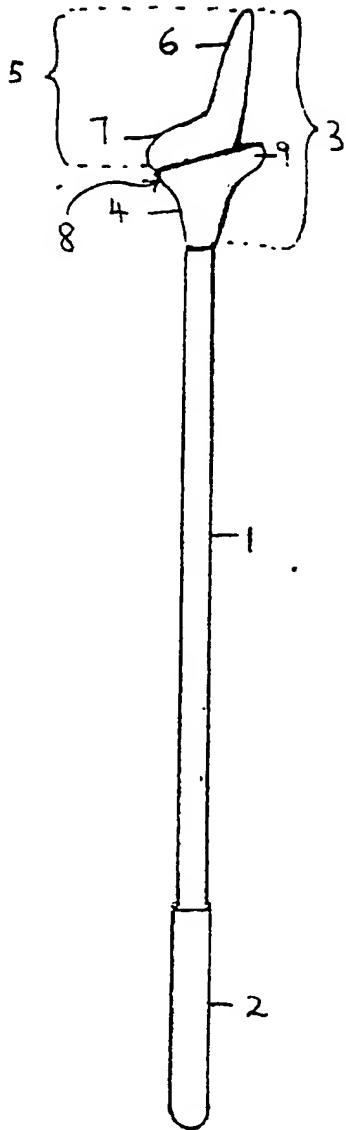
20 9. The cell sampler as claimed in any claim 1 to 8, wherein said vertical contact portion is connected to the horizontal contact portion by an attachment means.

25 10. The cell sampler as claimed in claim 9, wherein said attachment means could be the semi-tightened ball joint, any fasteners, screws, snaps, clamps, clips, nuts or other such equivalents.

Abstract

Precision contoured EXO/ENDOCervical cell sampler

5 An L-shaped, precision contoured EXO/ENDOCervical cell sampler for collecting representative cells is invented for pre-malignant and malignant diagnosis. The said cell sampler comprises of an elongated and rounded stick-shaped stem with a slightly thickened handle means at one end, and a flattened
10 connecting means having two protrusions at the other end. An L-shaped configuration at the root of said connecting means has one vertical ENDOCervical contact portion and one horizontal EXOCervical contact portion, which directly hug to the transformation zone thereby allowing a thorough and
15 complete 360 DEG rotational sweeping-up of all the truly representative cells. When said cell sampler is withdrawn from the cervix, the vertical ENDOCervical contact portion is subsequently bent and both the EXO- and ENDOCervical portions are swept across a microscope slide for cytological
20 microscopic examination.



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